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10/757,813

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Donald C. Roe

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THE PROCTER & GAMBLE COMPANY
Global Legal Department - IP
Sycamore Building - 4th Floor
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EXAMINER

REICHLE, KARIN M

ART UNIT

PAPER NUMBER

3761

MAIL DATE

DELIVERY MODE

07/19/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/757,813	Applicant(s) ROE ET AL.	
	Examiner Karin M. Reichle	Art Unit 3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 April 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3,6,7,10,11,16,17 and 19-23 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3,6,7,10,11,16,17 and 19-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Language Interpretation

1. The claim language is interpreted in light of the definitions set forth in the paragraph bridging pages 5-6 and page 27, lines 10-13. Any other claim terminology which has not been specifically defined will be interpreted in light of its broadest common definition, e.g. its dictionary definition. In claims 1 and 10 it is now claimed that the topsheet, backsheet, core, acceptance element and fecal storage element are all separate from each other yet are joined to define the article. This also now applies to the immobilization element now claimed in claim 10. Since “separate” as defined by the dictionary is “to differentiate or discriminate between; distinguish”, “dissimilar; distinct”, such claims are interpreted to require such structures/elements which are separate/distinguishable/distinct from each other yet are “joined” to define the article. However again note page 20, lines 18-22 of the instant specification and that the claims do not require that the elements are limited to performing a single function, i.e. it is not claimed that each individual element is the only element having such function and/or it has no other functions and/or all elements having such function are required to be an element as claimed. With regard to the claim terminology “fecal storage element”, Applicant’s 5-8-06 remarks refer to page 25, lines 8-10 of the instant application which sets forth that the storage element is a storage element which is “capable of storing viscous bodily wastes”. The remarks also refer to page 15, lines 25-27 of the application where a “viscous fluid bodily waste” is defined as “any waste discarded from the body having a viscosity greater than about 10cP and less than about 2x10 cP at a shear rate of one l/sec” in a controlled stress rheometry test. Lines

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15-18 of the same page 15 set forth that runny feces or menses are “viscous fluid bodily waste”. Finally, lines 29-31 of the same page 15 point out the viscosities of water and peanut butter for reference. In light of such disclosures, a “fecal storage element” as claimed will be interpreted as an element which is capable of storing fecal waste having a viscosity greater than about 10cP and less than about 2x10 cP at a shear rate of one l/sec in a controlled stress rheometry test. With regard to claims 1 and 10 it is noted that the claim now requires the storage element only include a “macroparticulate structure” having a multiplicity of particles and page 27, lines 22 et seq, i.e. only requires the element have at least two particles of a preferred size. See also discussion infra in paragraphs 3-4. With regard to claims 1 and 10 and new claims 20-23, note MPEP 714.02, second to last paragraph and Applicant’s remarks at page 6, section I and page 14, section IV. Also note the instant application at page 32, lines 1-3, esp. “should”, lines 17-19, esp. “capable of reducing the proclivity”, and lines 19-25, page 33, lines 5-11 and page 32, lines 9-14 and contrast to page 32, lines 14-15. Note also claims 21 and 23 do not require “Retention Under Compressed Inversion” values nor set forth how the claimed retention is measured, i.e. no specific test method set forth in claims nor instant application for retention claimed, i.e. according to any test method.

Claim Rejections - 35 USC § 103

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. Claims 1-3, 6-7, 10-11 and 16-17 and 19-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Thompson et al ‘208, (and thereby, by incorporation, Thompson ‘135,

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Kimberly-Clark EP '417, Ahr '045 (and thereby, by incorporation, Radel et al '314), Moore et al '642 and Lash et al '022).

Claim 1: See Claim Language Interpretation section supra, hereinafter referred to as CLI, and Thompson '208 at the Figures, col. 5, lines 39-44, col. 7, line 57-col. 8, line 6, col. 14, line 41-col. 19, line 2 (and thereby Thompson '135 at especially the Figures, the entire disclosure of EP '471, the entire disclosure of '045, esp. Figure 20 and the paragraphs bridging cols. 9-10 and 2-3, and thereby, '314 at Figures, esp. 11-12 and col. 18, last paragraph), col. 9, line 54-col. 14, line 38, col. 21, line 30-col. 22, line 2 (and thereby Moore '642 at col. 1, lines 46-62 and Lash et al '022 at col. 4, line 29-col. 6, line 35 and col. 14, lines 55-58 and 64 et seq), i.e. Thompson et al teaches a disposable absorbent article for wearing on or about a lower torso of a wearer for receiving bodily exudates which comprises (i.e. "joined", i.e. directly or indirectly, together to define such article), a "separate" topsheet, see CLI and, e.g., at least the distinguishable uppermost layer/laminate of 9, see cited portions of '045 and '314, a "separate" backsheet, see CLI and, e.g., 12, a "separate" absorbent core, see CLI and, e.g., at least one of the sheets of 11, a "separate" acceptance element, see CLI and, e.g., at least another distinguishable layer/laminate of 9, which comprises at least one aperture having an area of between 0.2 sq. mm to 25 sq. mm (See Thompson '208 at col. 15, line 61-col. 16, line 12 and the paragraph bridging cols. 18-19, i.e. EP '417 teaches filaments of a certain diameter, a topsheet having a certain number of filaments per square inch to define openings of equal size there between, i.e. the area between the filaments per sq. inch calculated from such disclosed specifics includes apertures having an area as claimed, note also discussion of 2) infra), and a "separate" storage element, see CLI and, e.g., 10 or another sheet of 11, between the acceptance element and the core, see also

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discussion of 3) infra, and the acceptance element, see discussion supra, is disposed between at least a portion of the topsheet and a portion of the fecal storage element (Note such does not require disposal directly adjacent such sheet and element). Claim 1 further requires 1) the storage element to have a compressive resistance of at least about 70%, 2) the apertures have an effective aperture size of between about 0.2 sq. mm to about 25 sq. mm and 3) the storage element being a “fecal storage element” and separate from the absorbent core. With regard to 1), while Thompson ‘208 teaches a layer 10 having resilience and a ratio of wet to dry caliper of at least 80%, and preventing flow interference while being form fitting and a layer 11 of curled, twisted, chemically stiffened and cross linked fibers, such fibers having increased dry resilience, i.e. the ability to return toward an expanded original state upon release of a compressional force applied thereto, and retaining their configuration during use at the portions cited supra, Thompson et al does not teach such layers having a “compression resistance” of at least about 70%. It is however noted that at page 29, lines 8-23 of the instant specification that Applicants while expressing the desire for the storage element to resist compression when a force is applied to maintain a significant level of storage capacity and restore itself to substantially its original thickness when the force is removed, does not disclose the criticality of the specific resistance claimed, i.e. the criticality of 70% rather than, for example, 45%. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to employ a compressive resistance of at least about 70% on the Thompson et al device since it has been held that where the general conditions of a claim are disclosed in the prior art as in the instant case, i.e. see discussion supra, it is not inventive to discover the optimum or workable ranges by routine experimentation. In re Aller, 105 USPQ 233. With regard to 2), see page 25, lines 2-5,

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of the instant application, and thereby Roe '338. Furthermore, see again the portions of Thompson '208 and EP '417 cited supra, i.e. the topsheet (see discussion of acceptance element with regard to Thompson '208 supra, i.e. "a 'separate' acceptance element, see CLI and, e.g., at least another distinguishable layer/laminate of 9, which comprises at least one aperture having an area of between 0.2 sq. mm to 25 sq. mm (See Thompson '208 at col. 15, line 61-col. 16, line 12 and the paragraph bridging cols. 18-19, i.e. EP '417 teaches filaments of a certain diameter, a topsheet having a certain number of filaments per square inch to define openings of equal size there between, i.e. the area between the filaments per sq. inch calculated from such disclosed specifics includes apertures having an area as claimed, note also discussion of 2) infra)'), of Thompson et al comprises or obviously comprises (Note MPEP 2131.03 and 2144.05) at least one aperture having an area of between 0.2 sq. mm to 25 sq. mm, e.g. apertures of equal size of such area, for enhanced acceptance of fluid. Therefore, it is the Examiner's first position that there is sufficient factual evidence for one to conclude that the topsheet, see again the discussion supra of the acceptance element and corresponding structure with respect to Thompson '208, of Thompson '208 would necessarily and inevitably include the claimed "effective aperture size" when tested according to the test set forth in Roe '338. Alternatively, i.e. the Examiner's second position, Thompson '208 teaches a topsheet which receives or accepts fluid, see again the discussion supra of acceptance element and corresponding structure with regard to Thompson '208. It is however noted that while at page 23, lines 19-25 of the instant specification Applicants express the desire for the acceptance element to pass waste there through, the criticality of the specific effective aperture size claimed enabling the element to do so is not set forth, e.g. the criticality of 30 sq. mm rather than 25 sq mm, for example, has not been set forth.

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Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to employ an effective aperture size as claimed on the Thompson et al device, if not already, since it has been held that where the general conditions of a claim are disclosed in the prior art as in the instant case, i.e. see discussion supra, it is not inventive to discover the optimum or workable ranges by routine experimentation. In re Aller, 105 USPQ 233. With respect to 3), see the Claim Language Interpretation section supra and, in addition to the portions of the prior art already cited, see also col. 1, line 11-13, col. 13, lines 43-45 and col. 31, lines 40-42 of '208 and col. 3, lines 28-29 of '022, i.e. "capable of absorbing...body waste fluids such as urine and feces", i.e. capable of absorbing/holding fluid feces. Therefore, it is the Examiner's first position that the prior art teaches a storage element 10 or a layer or sheet of 11 which is "separate" from 11 (as well as all portions of the topsheet) or the remainder of the sheets of 11 (as well as all portions of the topsheet and 10), respectively, and which element is capable of storing fecal waste having a viscosity greater than about 10cP and less than about 2×10^4 cP at a shear rate of one l/sec in a controlled stress rheometry test, i.e. "viscous fluid bodily waste", because '208 and '022 disclose articles and/or components thereof capable of absorbing /holding menses, i.e. a "relatively thick fluid" and/or fluid feces which as disclosed by the instant application are "viscous fluid bodily wastes". Alternatively, i.e. the Examiner's second position, since '208 and '022 disclose articles and/or components capable of absorbing/holding menses, i.e. a "relatively thick fluid", or fluid feces, there is sufficient factual evidence for one to conclude that such would necessarily and inevitably include a viscosity greater than about 10cP and less than about 2×10^4 cP at a shear rate of one l/sec when tested similarly to the claimed element, i.e. in a controlled stress rheometry test. Finally, i.e. the Examiner's third position, the

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prior art, at a minimum, discloses the desire that the article and/or components absorb/hold menses, i.e. a “relatively thick fluid” or fluid feces, i.e. relatively thick fluid bodily wastes, i.e. the same general conditions as those claimed. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to employ a storage element as claimed on the Thompson et al device, if not already, since it has been held that where the general conditions of a claim are disclosed in the prior art as in the instant case, i.e. see discussion supra, it is not inventive to discover the optimum or workable ranges, i.e. the claimed range of viscosity, by routine experimentation. In re Aller, 105 USPQ 233.

Claim 1 also requires 4) the fecal storage element be a macro-particulate structure comprising a multiplicity of particles, see CLI and, e.g., layer 11 includes layers having particles of a size, i.e. the shape of the particles spherical, i.e. area is dII, and the first paragraph of col. 15 of ‘022, e.g. particle size greater than 1410 microns or 1.4 mm, or, e.g., layer 10 includes fibers, i.e. particles, which have, e.g., inter-fiber spacings due to, e.g., curling/amplitude of the described size, and the discussion of claims 6 and 9 infra. (Note ‘208 at Figures, the paragraph bridging cols. 8-9, esp. col. 9, lines 14-23 (note the terminology “inter-fiber” as compared to “intra-fiber” and col. 9, lines 8-14 also), col. 12, lines 27-28 and 50-51, col. 1, lines 13-30, col. 13, lines 42-49, e.g., layer 10 includes fibers, i.e. particles, which are absorbent, see, e.g. col. 13, lines 43-49, having pores, e.g., inter-fiber spacings, having the claimed function, capability or property, i.e. lack of capillarity, and/or pores, e.g., inter-fiber spacings due to, e.g., curling/amplitude of the described size).

Finally claim 1 now requires 5) an immobilization element configured to retain bodily exudates, see CLI supra, and thereby the discussed portions of the instant specification, and, e.g.,

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another sheet or layer of 11 or a portion thereof, see again, e.g., '208 at col. 21, line 30-col. 22, line 2 (and thereby Lash et al '022, esp. '022 at col. 12, lines 2-13, col. 13 lines 13-44).

Claim 3: See portions of Thompson '208 and '135 cited with respect to claim 1 supra.

Claim 6: See portions of Thompson '208 with respect to claim 1 supra, e.g. layer 11 includes layers having absorbent particles of a size, i.e. the shape of the particles spherical, i.e. area is dII, and the first paragraph of col. 15 of '022, e.g. particle size greater than 1410 microns or 1.4 mm, or, e.g., layer 10 includes fibers, i.e. particles, which are absorbent, see, e.g. col. 13, lines 43-49, having pores, e.g., inter-fiber spacings, having the claimed function, capability or property, i.e. lack of capillarity, and/or pores, e.g., inter-fiber spacings due to, e.g., curling/amplitude of the described size.

Claim 7: See portions of Thompson '208 cited with respect to claim 1 supra, and paragraph bridging pages 28-29 of the instant application, i.e. layer 10 includes nonabsorbent, fibers, i.e. particles, with wettable surfaces, i.e. liquid insensitive fibers, which fibers have dimensions, see col. 12, lines 50-51.

Claims 2 and 10-11 and 16-17: Applicant claims the acceptance element having an effective open area of at least 30%. However, see page 25, lines 2-5, of the instant application, and thereby Roe '338. Furthermore, see again the portions of Thompson '208 and EP '417 cited supra, i.e. the topsheet of Thompson et al includes or obviously includes an open area of 30-60% for enhanced acceptance of fluid. Therefore, it is the Examiner's first position that there is sufficient factual evidence for one to conclude that the topsheet of Thompson '208 would necessarily and inevitably include the claimed "effective open area" when tested according to the test set forth in Roe '338. Alternatively, i.e. the Examiner's second position, Thompson '208

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teaches a topsheet which receives or accepts fluid. It is however noted that while at page 23, lines 8-13 of the instant specification Applicants express the desire for the acceptance element to pass waste therethrough, the criticality of the specific effective open area claimed enabling the element to do so is not set forth, e.g. the criticality of 30% rather than 28% for example has not been set forth. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to employ an effective open area of at least about 30 % on the Thompson et al device, if not already, since it has been held that where the general conditions of a claim are disclosed in the prior art as in the instant case, i.e. see discussion supra, it is not inventive to discover the optimum or workable ranges by routine experimentation. In re Aller, 105 USPQ 233. With regard to the last section of claim 10, see again the discussion of claim 1, esp. 5) and 3), i.e. the immobilization element is separate, e.g. separate from the remainder of the sheets of 11 (as well as all portions of the topsheet and 10), respectively,

Claim 19: See CLI and discussion of claims 1 and 6 supra and note that the language “about” allows some leeway with regard to the dimension it modifies, MPEP 2131.03 and 2144.05, i.e. the particles, see again CLI supra, i.e. at least two particles, as best understood have a nominal size of between about 2 mm and about 16 mm.

Claims 20 and 22: The immobilization element, see discussion of claim 1, is disposed between at least a portion of the fecal storage element, see discussion of claim 1 and the absorbent core, see discussion of claim 1.

Claims 21 and 23: The immobilization element is configured to retain greater than about 7.5 g of bodily exudates, see CLI supra and, e.g., the discussion of claim 1, 5), esp. the portions of ‘022 cited.

Response to Arguments

4. Applicant's remarks have been considered/reconsidered but are/still are deemed not persuasive for the reasons set forth supra, e.g. they are not commensurate in scope with the disclosure, the claim language, the prior art teachings, the prior art rejections an/or evidence of record. For example, see again Applicant's conclusory statements absent collaborating evidence, e.g. page 11, second full paragraph, and *In re Fitzgerald*, 619 F.2d 67, 70, 205 USPQ 594, 596 (CCPA 1980), i.e. the burden to show that materials are not substantially identical, in fact, is shifted to Applicant. For a second example, i.e. with respect to the first full paragraph on page 11, see discussion supra, e.g. "Furthermore, see again the portions of Thompson '208 and EP '417 cited supra, i.e. *the topsheet* (see discussion of acceptance element with regard to Thompson '208 supra, i.e. "a 'separate' acceptance element, see CLI and, e.g., at least another distinguishable layer/laminate of 9, which comprises at least one aperture having an area of between 0.2 sq. mm to 25 sq. mm (See Thompson '208 at col. 15, line 61-col. 16, line 12 and the paragraph bridging cols. 18-19, i.e. EP '417 teaches filaments of a certain diameter, a topsheet having a certain number of filaments per square inch to define openings of equal size there between, i.e. the area between the filaments per sq. inch calculated from such disclosed specifics includes apertures having an area as claimed, note also discussion of 2) infra))", of *Thompson et al* comprises or obviously comprises (Note MPEP 2131.03 and 2144.05) at least one aperture having an area of between 0.2 sq. mm to 25 sq. mm, e.g. apertures of equal size of such area, for enhanced acceptance of fluid." (Applicant's remarks in italics). The Examiner has now explicitly referred back to previously preceding portions of the rejection, i.e. contrary to the arguments the Office action addressed the acceptance element thereby. For a third example,

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Applicant's remarks on page 11-13 recite merely excerpts. Applicants attention is directed to the entirety of the rejection which set forth sufficient reasons/analysis. Finally with regard to section V, Applicants attention is invited to MPEP 1000. Attention is directed, however, also to the last sentence/paragraph of the following section 5.

Conclusion

5. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any new grounds of rejection were necessitated by the amendments to claims 1 and 10, the cancellation of claims 5 and 15 and the addition of claims 20-23.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karin M. Reichle whose telephone number is (571) 272-4936. The examiner can normally be reached on Monday-Thursday.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tanya Zalukaeva can be reached on (571) 272-1115. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Karin M. Reichle/
Primary Examiner, Art Unit 3761

July 15, 2010